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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,413	09/10/2003	Peter Kite	13317.1001cip	4621

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SPECKMAN LAW GROUP PLLC
1501 WESTERN AVE
SEATTLE, WA 98101

EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,413	KITE ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34,37,39-42,44-47 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32, 34, 37, 39-42, 44-47,54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 32, 34, 37, 39-42, 44-47, and 54-56 are pending. The Amendment received December 08, 2004, amended claims 32, 34, 37, 39, 40, 41, 42, 44-47, and added new claims 54-56. The Amendment also cancelled claims 33, 35, 36, 38, 43, and 48-53.

The Declaration filed on 12/08/2004 under 37 C.F.R. 1.132 has been received and entered into the file.

The provisional double patenting rejection of claims 32-48 under 35 U.S.C. 101 as claiming the same invention as that of claims 32-47 of copending Application No. 10/313,844 is herein withdrawn because applicant has submitted a Second Preliminary Amendment in co-pending application '844, and although the claims in these co-pending applications are based on similar subject matter, they are not claiming the same subject matter.

Applicant's Amendments to claims is sufficient to overcome the rejection of claims 32-36, 39-41 and 45, under 35 USC 102 (b) as being anticipated by Merck Index.

Applicant's Amendments to claims is sufficient to overcome the rejection of claims 32-43 and 45, under 35 USC 102 (b) as being anticipated by Kurginski (DE 1944363).

Applicant's Amendments to claims is sufficient to overcome the rejection of claims 32-43 and 45, under 35 USC 103 as being unpatentable over Merck Index and Kurginski (DE 1944363).

Applicant's Amendments to claims is sufficient to overcome the rejection of claims 44 and 46-48, under 35 USC 103 as being unpatentable over Merck Index and Cherepanov et al. in view of Remington's Pharmaceutical Sciences.

Election/Restrictions

Claims 48-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 8 2004.

The requirement is made **FINAL.**

Applicant's amendments necessitated the following new rejections.

Claim Objections

Claim 56 is objected to because of the following informalities:

The term "in" in line 5 of the claim is used twice.

Claims 34, 37, 39, 40, 42, 44, 45, 46, 47 are objected to because they depend on higher-numbered claims such as 54, 55, or 56.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 34, 37, 39, 40-42, 44-47, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word "safe" in claims 32 and 56 is vague because it is subjective, and all the other claims are rejected because they depend on either claim 32 or 56.

Claim 32, 34, 37, 39, 40-42, 44-47 are further rejected because the term "modest" in claim 32 is a relative term which renders the claim indefinite. The term "modest" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The term "substantially" in claim 40 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim 40 is further rejected because the term "agent" renders the claim indefinite. The term "agent" is not defined by the claim, the specification does not provide any information regarding an "agent", and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 34, 37, 40, 41, 42, 45, 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurginski (GB 1 279 148).

Kurginski teaches a method for cleaning soils that accumulate in toilets and sanitary facilities due to bacterial and fungal growth by applying to the surface a cleaning composition. See page 1, lines 12-15, lines 61-64. The composition comprises a chelating agent such as alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition. The PH of the composition is from 7 to 12. See page 2, lines 17-22, lines 48-52, lines 59-60; page 4, claims 1, 4, 5. See EXAMPLE 1, page 4, wherein tetrasodium salt of ethylenediaminetetraacetic acid is used.

While the references does not explicitly state that "composition has a bactericidal effect over a broad spectrum of microbes", as in claims 32, 54, 55, the Examiner respectfully points out that a compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Thus, since Kurginski teaches the

same tertasodium EDTA as that recited in the instant invention, the composition should possess the bactericidal effect over a broad range of microbes.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, the Examiner respectfully points out that a compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Thus, since Kurginski teaches the same tertasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

In claim 56, the intended use of a product or composition do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

It is respectfully pointed out that for the purposes of searching and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of ' will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of ", applicant has the burden of showing that the introduction of additional steps or

components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148) as applied to claims 32, 34, 37, 40, 41, 42, 45, 54-56 above, in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631).

Kurginski is as discussed above.

Kurginski does not teach a composition in a sterile condition in a single-dosage vial.

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3 and 6. Root further teaches a sterile polystyrene test tubes (vials) containing disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

It would have been obvious to a person of ordinary skill in the art to teach the composition of Kurginski in a sterile condition in a single-dosage vial from the teachings of Root.

Claims 39, 44, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148) as applied to claims 32, 34, 37, 40, 41, 42, 45, 54-56 above, in view of Remington's Pharmaceutical Sciences.

Kurginski et al. fail to recite

(i) a saline carrier for the EDTA injection,

(ii) employment of the composition in a sterile, pyrogen-free form

(iii) employment of the composition in a sterile condition in a prefilled syringe

Remington's Pharmaceutical Sciences teaches saline solutions as ideal for injection. Remington's Pharmaceutical Sciences warns against injection of solutions containing pyrogens (See page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments.

It would have been obvious to a person of ordinary skill in the art to be motivated to employ the claimed compositions without pyrogens, and with a carrier such as saline solutions as conventional with therapeutic regimen, and with conventional sterile protocols from the teaching of Remington's Pharmaceutical Sciences.

Conclusion

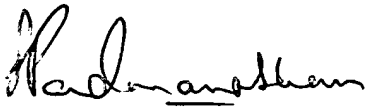
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER